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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,272	07/17/2003	Shanta M. Modak	070050.2429	4202

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EXAMINER

ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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07/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTS.COM

Office Action Summary	Application No. 10/622,272	Applicant(s) MODAK ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-13,15,31,32,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-13,15,31,32,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/28/2010, 2/26/2010, 3/3/2010, 6/15/2010.

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DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 4/21/2010, are acknowledged and entered. Claims 1, 3-9, 11-13, 15, 31-32, and 35-36 are pending and under examination.

Response to Arguments

Applicants' arguments, filed 4/21/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 1/28/2010, 2/26/2010, 3/3/2010, and 6/15/2010. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Objections

Claim 35 is objected to because of the following informalities:

- a) the claim recites "one or more *an* anti-microbial agent" in line 7. The wording is grammatically incorrect. The claim should read - - - one or more anti-microbial agents - - -;
- b) the claim recites "one or more agent" in line 12. The claim should read - - - one or more agents - - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.", (see MPEP § 2173).

Claim 35 recites an anti-irritant composition comprising (b) one *or more* an anti-microbial agent at a concentration of between 0.05% and 4% (weight/weight). When two or more of the recited antimicrobial agents are present in combination, it is unclear from the specification and claims whether the claimed concentration of between 0.05% and 4% (weight/weight) refers to the concentration of the individual antimicrobial agents or the combined amount of the antimicrobial agents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-9, 11-13, 15, 31-32, and 35-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-26 and 53-57 of U.S. Patent No. 7,745,425. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compositions would have been obvious over the compositions comprising two or more water-soluble zinc salts, each at a concentration of between about 0.05 and 5 percent and an effective amount of an antimicrobial and further comprising an emollient solvent at a concentration of less than 5 weight percent (claims 8-26) or a surgical hand wash comprising two or more water-soluble zinc salts, each at a concentration of between about 0.1 and 0.5 percent, farnesol, panthenol, and a quaternary ammonium compound and biguanide (antimicrobial agents) (claims 53-57).

Regarding inicroquat, the '425 patent teaches that inicroquat is a suitable emollient for use in the invention (col. 5, lines 36-40). See also the specific example formulations disclosed in the '425 patent.

The '425 patent specification further discloses the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients recited in the instant claims.

Claims 1, 3-9, 11-13, 15, 31-32, and 35-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 7,563,461 in view of USP No. 5,705,532. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compositions would have been obvious over the compositions comprising two or more water-soluble zinc salts, each at a concentration of between about 0.1 and 2 percent and further comprising water and one or more agent selected from the group consisting of a gelling agent, a thickening agent, a hydrophilic or hydrophobic polymer, an emulsifying agent, and an emollient. The skilled artisan would have been motivated to add one or antimicrobial agents to such a composition in view of the teachings of the '532 patent, which teaches antimicrobial compositions comprising less than

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or equal to two percent by weight chlorhexidine or chlorhexidine salt, less than or equal to 0.1 percent by weight of a quaternary ammonium compound such as benzalkonium chloride, and less than or equal to 2 percent by weight of parachlorometaxlenol (Abstract).

Regarding inicroquat, inicroquat is a well known emollient as disclosed in the instant application and the '461 patent (col. 7, lines 8-12). See also the examples in the '532 patent which teaches compositions comprising well known gelling agents, thickening agents, emulsifying agents, emollients, etc.

The '461 patent specification further discloses the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients recited in the instant claims.

Claims 1, 3-9, 11-13, 15, 31-32, and 35-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,435,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed compositions would have been obvious over the compositions comprising two or more organic salts zinc, wherein the organic salts of zinc are present at a combined concentration of between about 0.1 and 0.5 percent, farnesol, panthenol, and a quaternary ammonium compound and a second antimicrobial agent as recited in the '429 patent claims. Regarding inicroquat, the '429 patent teaches that inicroquat is a suitable emollient for use in the invention (col. 5, lines 6-10; Examples). The '429 patent specification further discloses the claimed gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents, and emollients recited in the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D. Anderson/

James D. Anderson, Ph.D.

Primary Patent Examiner, Art Unit 1614

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